

H&P Industries Recalls Povidone Iodine Products (9/11)

H&P Industries, Inc. recently announced a voluntary recall of ALL LOTS of Povidone Iodine Swabsticks, Povidone Iodine Prep Solutions, Povidone Iodine Scrub Solutions, and Povidone Iodine Prep Gel (lots beginning with 8J-8M, 9A-9M, 0A-0M, 1A-1C). This recall has been initiated at the request of the Food and Drug Administration (FDA).

The Povidone Iodine products were manufactured without having in place a system for microbial testing at the time of release, without having a system for testing of incoming components, and without having procedures designed and established to prevent objectionable microorganisms in these drug products. Patients undergoing medical and surgical procedures, including those who are immunocompromised, have a high risk of infection from antiseptic surgical preparations that have been prepared, packaged, or held under insanitary conditions. Although H&P Industries, Inc.'s investigation and extensive testing did not find contamination, and the products met H&P Industries, Inc., finished goods specifications, H&P Industries, Inc. is voluntarily recalling all Povidone Iodine Products. H&P Industries, Inc. has not received reports of adverse events or contamination attributed to these Povidone Iodine products.

Povidone Iodine Swabsticks, Povidone Iodine Prep Solutions, Povidone Iodine Scrub Solutions, and Povidone Iodine Prep Gel are labeled as an antiseptic for preparation of the skin before surgery, and are used to prevent infection in minor cuts, scrapes and burns. The Povidone Iodine Scrub solutions are labeled also for use as a surgical hand scrub for health-care personnel. The Povidone Iodine products were distributed nationwide to healthcare customers. The swabsticks are packaged in individual packets of one or three swabs and the Prep Solution, Scrub Solution and Prep Gel are sold in bottles.

Specific customers distributing the product and selling it at the wholesale and hospital level are reportedly being notified by e-mail with instructions on how to return the product. Consumers that have any of these types of products in their possession should not use the product and should return it to the place it was purchased. Consumers with questions can call H&P Industries, Inc. at (262) 538-2907.

Additional information is available on the FDA Web site by visiting:

www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm269800.htm.